FDA PLASMA STANDARDS WORKSHOP

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Plasma Specifications

- Octapharma uses different plasma types for

1. Production of SD-Plasma
2. Fractionation of coagulation factors and factor complex
3. Fractionation of IVIG and Albumin

Use of Plasma Qualities

Type	SD Plasma	F IX and Complex	F VIII	IVIG, Albumin
RP < 8h	x	x	x	x
SP	x	x	x	x
RP < 24h	-	-	x	x
RP < 72h	-	-	-	x

Plasma Specification Details

Type	Separate	Freeze	Store	Ship	Expires
RP < 8h	Whole Blood/ High Spin	< -30°C core T/1h	<-20°C	<-20°C	1 year
SP	Apheresis	< -30°C	<-20°C	<-20°C	2 years
RP < 24h	Whole Blood/ High Spin	< -30°C	<-20°C	<-20°C	2 years
RP < 72h	Whole Blood/ High Spin	< -30°C	<-20°C	<-20°C	2 years

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Yield Influencing Parameters – Coagulation Factors

- Time between blood collection and plasma separation
  - RP 8h and SP are preferred for labile products
  - RP 24h still acceptable for FVIII
- Method of plasma separation
  - Low cell contamination in plasma
  - Prevention of hemolysis
- Method of plasma freezing
  - SP → normal freezing process sufficient
  - RP 8h, RP 24h → shock freezing at < -30°C improves yield

Conclusion

- Octapharma plasma specifications are based on current Ph.Eur. regulations.
- For SD plasma, stricter requirements apply as a minimum level of defined coagulation factors must be achieved in the final product.
- For storage and transport of plasma, <-20°C are sufficient based on experience with the given expiration dates.